

Amendment to the Claims:

Please delete all prior listings of the claims and substitute therefor the listing of the claims as provided below:

Claims 1-10 (cancelled).

11. (currently amended) A The graft implant according to claim 10 comprising any one or combinations of allograft materials, autograft materials, xenograft materials, synthetic materials, metallic materials assembled into a an assembled implant which is assembled into a single graft by use of reinforcing material to hold the constituent pieces of graft materials together, wherein said any one or combinations of allograft materials, autograft materials, xenograft materials, synthetic materials, metallic materials are pretreated by a process comprising cleaning, perfusion and passivation process which comprises cyclic exposure of said implant to increased and decreased positive or negative pressures, or both, wherein a cleaning solution used during the cleaning step is selected from the group consisting of: sterile water, Triton X-100, TNBP, 3% hydrogen peroxide, a water-miscible alcohol, saline solution, povidone iodine, ascorbic acid solution, aromatic or aliphatic hydrocarbons, ethers, ketones, amines, urea, guanidine hydrochloride, esters, glycoproteins, proteins, saccharides, enzymes, gaseous acids, or peroxides, and mixtures thereof.

12. (currently amended) The graft implant according to claim 6 11 wherein the assembled implant is pretreated or treated after assembly to incorporate biologically active or inert materials.

13. (original) An implant comprising segments of cortical bone, cancellous bone, cortical-cancellous bone, or combinations thereof pinned to each other by means of cortical bone pins, wherein, prior to assembly or after assembly, the graft materials are soaked,

infused, impregnated, coated or otherwise treated with bone morphogenetic proteins (BMPs), antibiotics, growth factors, nucleic acids, peptides, or combinations thereof.

14. (currently amended) The implant according to claim 6 11 comprising an assembled cancellous block, or dowel, harvested from the iliac crest or another suitable site to form a Cloward Dowel, iliac crest wedge, or cancellous bone block, dowel, reinforced by insertion therein of cortical bone pins.

15-29 (cancelled)

30. (original) An assembled graft implant comprising two or more individual segments fastened together, said implant comprising at least one demineralized bone segment and at least one mineralized bone segment.

31. (original) The assembled graft implant of claim 30, wherein said at least one demineralized bone segment comprises a region of mineralized bone.

32. (original) The assembled graft implant of claim 30, wherein said demineralized or mineralized segments are made from cortical bone, cancellous bone or both.

33. (original) An assembled graft implant comprising two or more individual segments fastened together, said implant comprising at least one synthetic segment and at least one demineralized bone segment.

34. (original) The assembled graft implant of claim 33, wherein said demineralized bone segment comprises a region of mineralized bone.

35. (original) The assembled graft implant of claim 33, wherein said synthetic segment is comprised of stainless steel, titanium, cobalt chromium-molybdenum alloy, nylon, polycarbonate, polypropylene, polyacetal, polyethylene oxide and its copolymers, polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS), polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes), poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone) (PGA/PCL), poly(phosphase ester), polyanhydrides, polyvinyl alcohol, hydrophilic polyurethanes, and a combination of one or more bioabsorbable polymers.

36. (original) The assembled graft implant of claim 33, wherein said at least one synthetic segment comprises a first end and a second end, and wherein a demineralized bone segment or a mineralized bone segment is attached to said first end or said second end.

37. (original) An assembled graft implant comprising two or more individual segments fastened together, said implant comprising at least one synthetic segment and at least one mineralized bone segment.

38. (original) The assembled graft implant of claim 37, wherein said synthetic segment is comprised of stainless steel, titanium, cobalt chromium-molybdenum alloy, and a plastic of one or more members selected from the group consisting of nylon,

polycarbonate, polypropylene, polyacetal, polyethylene oxide and its copolymers, polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS), polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes), poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone) (PGA/PCL), poly(phosphase ester), polyanhydrides, polyvinyl alcohol, hydrophilic polyurethanes, and a combination of one or more bioabsorbable polymers.

39. (currently amended) The An assembled graft implant of claim 11 comprising two or more individual segments fastened together, wherein said assembled graft comprises at least one segment comprised of demineralized bone, mineralized bone, demineralized bone having a mineralized region, or a synthetic material, and at least one other segment fastened thereto that is comprised of demineralized bone, mineralized bone, demineralized bone having a mineralized region, or a synthetic material.

40. (original) A graft segment configured for assembly with at least one other segment, wherein said graft segment comprises at least one mineralized bone region and at least one demineralized bone region.

41. (original) The graft segment of claim 40, wherein said mineralized bone region is attached to or integrated with said demineralized bone region.

42. (original) A graft segment according to claim 40, wherein said graft segment comprises a central mineralized bone region and at least one demineralized bone region

integrated with said central mineralized bone region and positioned on one or more sides of or surrounding said mineralized bone region.

43. (original) A mixed composition segment configured for assembly with at least one other segment, said mixed composition segment comprising a region comprised of mineralized bone, demineralized bone or a synthetic material that is attached to or integrated with another region comprised of mineralized bone, demineralized bone or a synthetic material.

44. (original) The mixed composition segment of claim 43, additionally assembled with at least one other graft segment.

45-47 (cancelled)

48. (currently amended) A mixed-composition segment produced cleaned by the method of claim 45 comprising cyclically exposing said implant to increased and decreased positive or negative pressures, or both, wherein a cleaning solution used during the cleaning step is selected from the group consisting of: sterile water, Triton X-100, TNBP, 3% hydrogen peroxide, a water-miscible alcohol, saline solution, povidone iodine, ascorbic acid solution, aromatic or aliphatic hydrocarbons, ethers, ketones, amines, urea, guanidine hydrochloride, esters, glycoproteins, proteins, saccharides, enzymes, gaseous acids, or peroxides, and mixtures thereof.

49. (currently amended) A mixed-composition segment produced by the method of claim 45 48, wherein at least one region of said mixed-composition segment is mineralized bone, and at least one region of said mixed-composition segment is demineralized bone.

50. (currently amended) A mixed-composition segment ~~produced by the method~~ of claim 45 48, wherein one region of said mixed-composition segment is mineralized, and one or more regions of said mixed-composition segment are demineralized, wherein said one or more ~~regions~~ segments of demineralized bone surround or sandwich said region of mineralized bone.

51. (original) A method for manufacture of a mixed-composition segment for autograft, allograft and xenograft graft implants comprising a. contacting a first piece of graft material comprising bone with a demineralizing solution for a period of time sufficient to achieve a desired level of demineralization to said first piece; and b. bonding or otherwise intimately attaching a portion (region) of said first piece of demineralized graft material with a second piece of graft material, said second piece of graft material being mineralized, demineralized, or synthetic, such that said bonding or intimately attaching results in a single integral mixed-composition segment; and c. optionally, removing a sufficient quantity of said demineralizing solution from said first region to prevent a toxic or an inflammatory response to said segment upon implantation into a patient in need thereof.

52. (original) The method of claim 51, wherein step (a) is repeated for at least one additional piece, and step (b) is repeated to attach each at least one additional piece to form a multi-piece (multi-region) mixed-composition segment.

53. (original) A mixed-composition segment produced by the method of claim 51.

54. (original) A mixed-composition segment produced by the method of claim 51, wherein at least one region of said mixed-composition segment is mineralized bone, and at least one region of said mixed-composition segment is demineralized bone.

55. (original) A mixed-composition segment produced by the method of claim 51, wherein one region of said mixed-composition segment is mineralized bone, and one or more regions of said mixed-composition segment are demineralized bone, wherein said demineralized bone regions surround or sandwich said region of mineralized bone.

56. (original) A kit comprising assemblable parts of autograft, allograft, xenograft and synthetic segments for assembling mixed-composition implants from smaller pieces of graft materials to form a larger graft implant product which may be formed in the course of a surgical procedure to precisely meet the needs of a given patient or procedure, and comprising at least one mixed-composition segment among said assemblable parts.

57-59. (cancelled)

60. (original) An implant comprising segments of cortical bone, cancellous bone, cortical-cancellous bone, or combinations thereof pinned to each other by means of cortical bone pins, wherein, prior to assembly or after assembly, the graft materials are soaked, infused, impregnated, coated or otherwise treated with bone morphogenetic proteins (BMPs), antibiotics, growth factors, nucleic acids, peptides, sodium hyaluronate, hyaluronic acid, polysulfated glycosaminoglycans, or combinations thereof, and wherein, at least one of said segments is a mixed-composition segment or demineralized bone.

61. (original) An assembled implant comprising a first bone segment pinned to a second bone segment, and comprising a flexible tissue affixed between said first bone segment and said second bone segment, wherein said first bone segment is a mixed-composition segment.

62. (original) An assembled implant bone graft comprising at least two individual segments joined together, and synthetic scaffolding material, wherein said synthetic

scaffolding material passes through and/or surrounds said segments, thereby providing structural support to at least one of said at least two individual segments.

63. (original) An assembled bone graft comprising: a. a first graft segment comprising at least one mineralized bone region, and at least one demineralized bone region; and comprising at least one hole; b. at least one other graft segment comprising at least one hole; and c. at least one connector; d. whereby the first graft segment and the at least one other graft segment are joined physically by said at least one connector.

64. (original) The bone graft of claim 63, wherein said first graft segment and said at least one other graft segment are joined physically by means of at least one pin, rod, bar, post or other linear connector passing through said at least one hole in said first graft segment which is arranged to align with said at least one hole of said other graft segment.

65. (original) The bone graft of claim 63, additionally comprising a synthetic support structure that encompasses all or a part of said composite bone graft whereby the synthetic support structure bears load that would otherwise bear on at least one of said graft segments.

66. (original) The bone graft of claim 65, wherein said synthetic support structure is comprised of a biocompatible material selected from the group consisting of stainless steel, titanium, cobalt chromium-molybdenum alloy, and a plastic of one or more members selected from the group consisting of nylon, polycarbonate, polypropylene, polyacetal, polyethylene oxide and its copolymers, polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC),

polydioxanone (PDS), polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes), poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone) (PGA/PCL), poly(phosphase ester), polyanhydrides, polyvinyl alcohol, hydrophilic polyurethanes, and a combination of one or more bioabsorbable polymers.

67. (original) A graft implant comprising any one or combinations of allograft materials, autograft materials, xenograft materials, synthetic materials, and metallic materials assembled into an assembled implant which is assembled into a single graft by use of reinforcing material to hold the constituent pieces of graft materials together, and comprising at least one mixed-composition segment.

68. (original) The graft implant of claim 67 wherein said reinforcing material comprises cortical bone.

69. (original) The graft implant of claim 67 wherein the assembled implant is pre-treated or treated after assembly to incorporate biologically active or inert materials.

70. (original) The implant of claim 67 comprising an assembled cancellous block, or dowel, harvested from the iliac crest or another suitable site to form a Cloward Dowel, iliac crest wedge, or cancellous bone block, dowel, reinforced by insertion therein of cortical bone pins.

71. (original) The implant of claim 67 comprising a cortical bone implant reinforced by insertion therein of at least one cortical bone pin.

72. (original) The implant of claim 67 comprising an assembled implant comprising different segments of cortical bone, cancellous bone or both.

73. (original) The implant of claim 67 in the form of a tapered dowel.

74. (original) The implant of claim 67 comprising an assembled implant comprising different segments of cortical bone, cancellous bone, demineralized cortical or cancellous bone, or synthetic material, or combinations thereof.

75. (original) The implant of claim 71 wherein insertion of reinforcing pins provides an implant with multiple load-bearing pillars.

76. (original) The implant of claim 75 wherein said pins protrude from the surface of the implant to engage with inferior, superior or both surfaces of bone between which the implant is inserted.

77. (original) The implant of claim 67 which is a spinal implant.

78. (currently amended) The implant according to claim 67 comprising a cancellous portion of bone implant that has been compression molded, and then affixed to other portions of cortical or cancellous bone ~~machined according to different or similar principles~~.

79. (original) A bone implant comprising:

- a. two or more bone segments,
- b. at least one biocompatible connector,
- c. wherein said at least one biocompatible connector fastens together said two or more bone segments to form an assembled bone implant, said at least one biocompatible connector does not comprise an adhesive.

80. (original) The bone implant of claim 79, wherein at least one of said two or more bone segments is a mixed composition segment.

81. (original) An assembled bone graft comprising at least three segments, each said segment comprising a first edge and a second edge at a side opposite from the first edge, the first and second edges having interlocking structures mateable with an adjacent edge of an adjacent segment, whereby each said segment's first and second edges interlock with the edges of adjacent segments.

82. (original) An assembled bone graft comprising at least three non-coplanar segments, each said segment comprising a first mateable edge and a second mateable edge, each of said mateable edges being mateable with an adjacent mateable edge of an adjacent segment, whereby said assembled bone graft is assembled by mating said first edges and said second edges of said segments positioned adjacent to one another.

83. (original) The assembled bone graft of claim 82, wherein said mateable edges interlock, and are selected from the group of joint types consisting of ball and socket, tongue and groove, and mortise and tenon.

84. (cancelled)

85. (original) The assembled bone graft of claim 82, wherein at least one of said segments is comprised of a material selected from the group consisting of demineralized bone, mineralized bone, a combination of demineralized and mineralized bone.

86. (original) The assembled bone graft of claim 82, wherein at least one of said segments is comprised of a material selected from the group consisting of cortical bone, cancellous bone, and a combination of cortical and cancellous bone.

87. (currently amended) The assembled bone graft of claim 82, wherein at least one of said segments is comprised of ~~any one or combinations of allograft materials, autograft materials, xenograft materials, synthetic materials, and metallic materials assembled into a segment.~~

88. (original) An assembled bone graft comprising a first and a second arcuate-shaped segment, each segment comprising two interlocking edges, whereby each said edge of said first segment interlocks with an edge of said second segment, forming an assembled bone graft with an open channel between said first and second segments.

89. (currently amended) A bone tendon bone type graft useful in orthopedic surgery comprising at least one bone block and a flexible band attached to said at least one block at least one cortical bone pin in said bone block, wherein said bone graft is cleaned by the method of claim 45 comprising exposing said implant to a cleaning solution under cyclic positive and negative pressures.

90 – 101 (cancelled)